K020946

IV. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

APR 0 4 2002

Submitter

Company: ..... 3M ESPE AG

Street: ..... ESPE Platz

ZIP-Code, City: ..... D-82229 Seefeld

Federal State: ..... Bavaria

Country: ..... Germany

Establishment Registration Number: 9611385

Contact: ..... Dr. Andreas Petermann
Manager U.S. Regulatory Affairs

Phone: 01149-8152-700 1395

Fax: 01149-8152-700 1869

E-mail: ..... Andreas.Petermann@mmm.com

Date of Submission: ..... March 22, 2002

Name of Device

Proprietary Name: ..... Adper Prompt

Classification Name: ..... Resin Tooth Bonding Agent

Common Name: ..... Dental Adhesive

Predicate Device:

Prompt L-Pop ..... K 001494

Description for the Premarket Notification

Adper Prompt is classified as a Resin Tooth Bonding Agent (21 C.F.R. § 872.3200) because it is a device intended to be painted on the interior of a prepared cavity of a tooth to improve retention of restorative materials (compomer and composite restorative material).

3M ESPE is submitting this Special 510(k) for modifications to the All-In-One Adhesive Prompt L-Pop.

The modifications of Prompt L-Pop concern minor changes of the chemical composition, however, the basic chemical design remains the same.

Like Prompt L-Pop, Adper Prompt will be available in single dose applicators, "Adper Prompt L-Pop". Additionally, Adper Prompt will also be available in a two-vial version called "Adper Prompt". The resulting bonding agent, regardless if obtained from L-Pop application system or two-vial system, has the same chemical composition and material characteristics.

The modified bonding agent Adper Prompt has the following similarities to the unmodified Prompt L-Pop:

- Adper Prompt has the same intended use.
- Adper Prompt incorporates the same basic chemical design.
- Adper Prompt has the same shelf life.

To provide evidence for safety, the chemical composition of Adper Prompt was compared to Prompt L-Pop. Additionally, an independent research institute carried out biocompatibility testing. The results show that Adper Prompt is a safe device.

To prove the effectiveness of Adper Prompt, the performance characteristics of Adper Prompt were compared to Prompt L-Pop.

In summary, the modified dental adhesive Adper Prompt described in this Special 510(k) premarket notification submission is, in our opinion, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Andreas Petermann
Manager, U.S. Regulatory Affairs
3M ESPE AG
ESPE Platz
D-82229 Seefeld
Bavaria,
GERMANY

APR 0 4 2002

Re: K020946
Trade/Device Name: Adper Prompt
Regulation Number: 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Codes: KLE and EMA
Dated: March 22, 2002
Received: March 25, 2002

Dear Dr. Petermann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

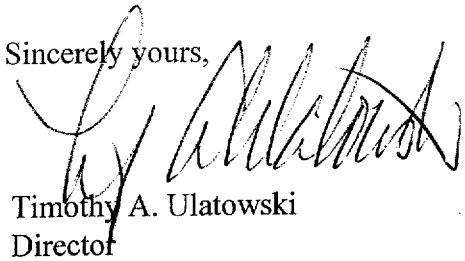
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

(As Required by 21 C.F.R. § 801.109)

510(k) Number: K020946

Device Name: Adper Prompt

Indications for use:

Bonding between dentin/enamel and composite filling materials.

Bonding between dentin/enamel and compomer filling materials.

Bonding mediator for fissure sealing

Bonding mediator for bracket attachment

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020946

Prescription use: ☐ Over-the counter use ☐